REMARKS

Claims 1-3, 5-10, 13, 15-18, 20-23 and 32-39 are currently pending. Claims 4, 11, 12, 14, 19 and 24-31 were previously cancelled and claim 36 is currently cancelled. Applicants reserve the right to prosecute claim 36 in an application claiming priority to the present application. Claim 1 is amended to remove the limitation of a syringe, and this limitation is placed in new independent claim 39. The present claims are directed to a drug delivery device having a non-coring needle on the distal end of a catheter or syringe that minimizes or prevents damage to the site at which the needle is inserted and methods of use.

Claim Rejections – 35 USC 112, 1st paragraph

Claims 6-10 are rejected as allegedly failing to comply with the written description requirement. The Examiner states that there "is no teaching of a distal end with first and second extensions that are non-pointed, therefore this subject matter is drawn to figures 3-6." Although Figures 3-6 are illustrated as having a pointed tip, the specification states in paragraph [0043] that "each of the disclosed aspects and embodiments of the present invention may be considered individually or in combination with other aspects, embodiments, and variations of the invention." Since Figures 1, 2, 7 and 8 are shown as having a curvilinear blunt tip, as described in paragraph [0019], there is adequate written description for such a curvilinear tip being used in combination with the other aspects of Figures 3-6.

Claim Rejections – 35 USC 102

A. Rejection of Claims over Magasi

Claims 1, 2, 6-10 and 32-38 stand rejected under 35 U.S.C. 102(b) as being allegedly anticipated by US Patent No. 4,826,492 to Magasi ("Magasi"). Applicants traverse this rejection because Magasi does not describe each and every element of the claims. Specifically, at the least, Magasi does not describe "a catheter having a distal portion, and a needle attached to the distal portion," as recited in claim 1.

The Examiner apparently relies on Figure 6 to reject independent claims 1, 34, 36 and 37 and argues that in Magasi "the catheter is being interpreted as the proximal portion [of shank 1]." Applicants submit that this is simply not a reasonable interpretation of the term "catheter" to

which a needle is attached. By arguing that a portion of shank 1 in Figure 6 is a catheter, the Examiner is interpreting shank 1 as a single unitary device that has an arbitrary portion that is a catheter and an arbitrary portion that is a needle. One skilled in the art would not interpret the proximal portion of shank 1 in Figure 6 as a catheter. As Applicants have argued before, Figure 6 shows an intermediate product , and not an end product (probe 10). Figure 6 is described as "illustrating the method of *manufacture* of the probe of FIG.1" (col 3, lines 67-68). To state that the catheter is portion of an intermediate manufacturing product ignores the basic definition of a catheter.

A catheter has a specific medical definition that would be known to one of ordinary skill in the art. [See Exhibit A attached.] Dorland's Illustrated Medical Dictionary defines a catheter as "a tubular, flexible, surgical instrument that is inserted into a cavity of the body to withdraw or introduce fluid." Stedman's Medical Dictionary defines a catheter as "a tubular instrument to allow passage of fluid from or into a body cavity or blood vessel." Encyclopedia Britannica defines catheterization as "[t]hreading of a flexible tube (catheter) through a channel in the body to inject drugs or a contrast medium, measure and record flow and pressures, inspect structures, take samples, diagnose disorders, or clear blockages." Thus, a catheter must be capable of being safely inserted into a body, which means it must be sterile, as would be known to one of ordinary skill in the art. Since an intermediate product of manufacturing is not inserted into the body, it is not sterile, and thus it cannot be interpreted as including a "catheter". For at least these reasons, Applicants submit that an express limitation of the claims is not described by Magasi and Applicants request withdrawal of this rejection.

Magasi also does not describe a syringe, as recited in claims 34, 37 and new claim 39. It is noted that the Examiner does not present any arguments regarding this limitation.

Applicants also add that there is no motivation to take the shank of Figure 6 and attach it to a catheter or syringe, since shank 1 of Figure 6 is an intermediate product and it makes no sense to add a catheter or syringe (which are components that are used with end products when drug delivery is desired) to an intermediate product. Indeed, to use an intermediate product together with a final product would inherently go against the teaching of Magasi.

Furthermore, if the Examiner looks to the final finished needle of Magasi, he will find that several of the limitations of the independent claims are not met.

At least furthermore, with respect to claim 1, Magasi does not disclose a drug delivery device with a curvilinear blunt tip. The end product shown in Figures 1 and 2 clearly does not show a "curvilinear blunt tip". Magasi describes tip 2 as a "puncturing tip" and it is clearly illustrated in Figs. 1 and 2 as a sharp point. Thus, Magasi does not describe a drug delivery device with a curvilinear blunt tip.

At least furthermore, with respect to claim 34, Magasi does not disclose a drug delivery device having a needle with a shaft having a first surface indented towards a second surface to define a distal opening. The Examiner relies upon Figure 6 of Magasi for the basis of his argument. Although the "first surface [may be] indented toward to second surface," in Figure 6, this drawing illustrates an intermediate stage in the method of manufacture, not a final product. In the final product, there is no indented surface, since "the shank section is then machine ground rearwardly from contact point 24 at an angle to thus form lateral openings 20 and 22 and a displacement surface 4 from the V-shaped channel 26" (col 7, lines 13-16). The final product is shown in Figures 1 and 2, and this product does not include an indented surface. Thus, Magasi does not disclose a drug delivery device having a needle with a shaft having a first surface indented towards a second surface to define a distal opening.

At least furthermore, with respect to claim 37, Magasi does not disclose a drug delivery device having a needle with a shaft having a first surface indented towards a second surface at an angle α and the second surface being indented towards the first surface at an angle β, wherein the angle α is equal to the angle β. As can be clearly seen in Figure 1, even if the first surface may be interpreted as being indented toward the second surface (which it cannot as described above), there is clearly no corresponding indentation of the second surface towards the first surface. Thus, Magasi cannot form a distal opening with an hourglass shape, as recited in claim 38.

Claim 36 has been cancelled, thus this rejection is moot.

B. Rejection of Claims over Dye

Claims 34-38 stand rejected under 35 U.S.C. 102(b) as being allegedly anticipated by US Patent No. 3,788,320 to Dye ("Dye"). However, Dye does not describe all the limitations of claims 34 and 37 (and all claims dependent therefrom).

First, with respect to all these claims which recite a syringe or catheter in combination with a needle, Dye does not disclose a drug delivery device comprising a catheter or syringe in

combination with the spinal needle, which are express limitations of claims 34 and 37. It is noted that the Examiner completely ignores this new claim limitation, as there are no relevant rejections.

Moreover, with respect to all these claims that recite a distal opening, Dye does not disclose this limitation. Dye describes a spinal needle comprising a hollow outer needle (12) and a stylet removably insertable therein that has a generally closed piercing end 32. The Examiner improperly interprets the two side bevel faces 40 and 42 in Dye as a distal opening. As clearly described by Dye, the face 40, face 42, and heel face 62 of stylet 22 inserted into needle 12 form a closed tip, thus there are no openings (column 2, lines 49-60).

The Examiner cites column 3, lines 39-43 as Dye's disclosure of a distal opening, however this simply states that when the stylet 22 is removed, the outer needle 12 has a distal opening. However, once the stylet is removed, there is no description of the form of this resulting opening. Additionally, if the resulting opening was the same form as the removed stylet, which is not conceded, the slanted surface of the tip would result in a projected area of the opening that is actually larger than the cross-sectional area of a section of the shaft proximal to the distal end, not a smaller projected area as claimed by claims 34-38

For at least these reasons, Applicants submit that Dye does not anticipate claims 34, 35, 37, and 38 and Applicants request withdrawal of this rejection. Claim 36 is cancelled, thus this rejection is moot.

Claim Rejections – 35 USC 103

A. Rejection of Claims over Magasi in view of Alchas

Claims 3, 5 and 12 (which depend directly or indirectly from claim 1) stand rejected under 35 U.S.C. 103(a) as being allegedly rendered obvious over Magasi in view of US Patent No. 4,537,593 to Alchas ("Alchas"). As stated above, Magasi does not describe all the limitations of claim 1. Alchas does not make up for these deficiencies. Alchas does not describe a catheter, and further does not describe a needle having a distal-most end that is a curvilinear blunt tip. The tip of Alchas is clearly the endpoint of two straight lines. Alchas states that the closed planar portion 31 "terminates at a straight edge 32 lying at an angle to longitudinal axis 34" (see col. 5, lines 42-46). Further, Alchas states that "flat portion 31 includes a tapered

portion 35 which is tapered toward straight edge 32 in a razor-like fashion" (see col. 5, lines 53-55). For at least these reasons, Applicants submit that claims 3 and 5 are not rendered obvious over Magasi in view of Alchas, and Applicants request withdrawal of this rejection. Applicants note that claim 12 was previously cancelled, thus this rejection is moot.

B. Rejection of Claims over Altman

Claims 11 and 13-16 (which depend directly or indirectly from claim 1) stand rejected under 35 U.S.C. 103(a) as being allegedly rendered obvious over US Patent No. 6,346,099 to Altman ("Altman"). It is noted that the Examiner does not state that the claims are rejected over Magasi in view of Altman, however the Examiner's discussion appears to indicate such. As stated above, Magasi does not describe all the limitations of claim 1. Although Altman describes a catheter, there is no motivation to combine a catheter with the intermediate product of Magasi shown in Figure 6, as discussed above. For at least this reason, Applicants submit that claims 13, 15 and 16 are not rendered obvious over Altman and Magasi, individually or together. As such, Applicants request withdrawal of this rejection. Applicants note that claims 11 and 14 were previously cancelled, thus this rejection is moot.

C. Rejection of Claims over Magasi in view of Luther

Claims 17-20 (which depend directly or indirectly from claim 1) stand rejected as being allegedly rendered obvious over Magasi in view of US Patent No. 5,873,864 to Luther ("Luther"). As stated above, Magasi does not disclose all the limitations of claim 1. Although Luther describes a catheter, there is no motivation to combine a catheter with the intermediate product of Magasi shown in Figure 6, as discussed above. For at least this reason, Applicants submit that claims 17, 18 and 20 are not rendered obvious by the combination of Magasi and Luther. As such, Applicants request withdrawal of this rejection. Applicants note that claim 19 was previously cancelled, thus this rejection is moot.

D. Rejection of Claim over Magasi in view of Gross

Claim 21 (which depends from claim 1) stands rejected under 35 U.S.C. 103(a) as being allegedly rendered obvious over Magasi in view of US Patent No. 5,843,048 to Gross ("Gross"). As stated above, Magasi does not describe all the limitations of claim 1. Gross does not make up

for these deficiencies. Gross describes an epidural needle having a "blunted tip" (40) through which a catheter can be inserted. Although Gross includes a catheter and a needle, the needle is not connected to the distal end of the catheter, rather the catheter is inserted through the needle. Thus, Gross cannot cure the deficiencies of Magasi. Furthermore, there is no motivation to combine a catheter with the intermediate product of Magasi shown in Figure 6, as discussed above. For at least these reasons, Applicants submit that claim 21 is not rendered obvious over Magasi in view of Gross. Accordingly, Applicants request withdrawal of this rejection.

E. Rejection of Claims over Magasi in view of Johnson

Claims 22 and 23 stand rejected as being allegedly rendered obvious over Magasi in view of US Patent No. 5,817,052 to Johnson ("Johnson"). As stated above, Magasi does not describe all the limitations of claim 1. Johnson does not make up for these deficiencies. Johnson does not describe a catheter. For at least this reason, Applicants submit that claim 21 is not rendered obvious by the combination of Magasi and Johnson. As such, Applicants request withdrawal of this rejection.

CONCLUSION

It is respectfully submitted that the present application is now in condition for allowance, which action is respectfully requested. The Examiner is invited to contact Applicants' representative to discuss any issue that would expedite allowance of the subject application.

Any fees for extension(s) of time or additional fees required in connection with the filing of this response, are hereby petitioned under 37 C.F.R. § 1.136(a), and the Commissioner is authorized to charge any such required fees or to credit any overpayment to Kenyon & Kenyon's Deposit Account No. 11-0600.

Respectfully submitted,
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